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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte IAN CARROLL, DAVID CLARK, and SEAN MACKEY

Appellants

Appeal 2009-009980
Application 10/587,535
Technology Center 1600

Decided: January 26, 2010

Before RICHARD TORCZON, MICHAEL P. TIERNEY, and SALLY GARDNER LANE, *Administrative Patent Judges.*

LANE, *Administrative Patent Judge.*

DECISION ON APPEAL

I. STATEMENT OF THE CASE

The appeal, under 35 U.S.C. § 134(a), is from a Final Rejection of Appellants' claims 1-10 and 12. Appellants cancelled claims 11 and 13-16. (App. Br. 1). We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Appellants' application is directed to methods of treating pain or cardiovascular conditions by creating an extended sympathetic nerve block

with a neurotoxin administered to a sympathetic ganglion. (Spec. ¶¶ [19] – [22]).

The Examiner relied on the following U.S. Patent Application Publications:

Donovan	2001/0023243	September 20, 2001
Brushey	2001/0056275	December 27, 2001

The Examiner also relied on the following publications:

- Henrard, et al., *Thoracic Sympathectomy for Prinzmetal Angina with Normal Coronary Arteries*, 75 ARCH. MAL. COEUR, 1317-20 (1982) (English abstract) ("Henrard");
- Erickson & Hogan, *CT-guided Injection of the Stellate Ganglion: Description of Technique and Efficacy of Sympathetic Blockade*, 188 RADIOLOGY, 707-09 (1993) ("Erickson"); and
- Kim et al., *Effects of Botulinum Toxin Type A on the Superior Cervical Ganglia in Rabbits*, 102 AUTONOMIC NEUROSCIENCE: BASIC AND CLINICAL, 8-12 (2002) ("Kim").

Claims 1-3 and 5-6 were rejected under 35 U.S.C. § 103(a) over Kim and Donovan. Appellants did not argue for the separate patentability of any of these rejected claims. We focus on claim 1 in our review. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Claims 1-6 were rejected under 35 U.S.C. § 103(a) over Kim, Donovan, and Brushey. Appellants did not argue for the separate patentability of any of these rejected claims.

Claims 1-3 and 5-7 were rejected under 35 U.S.C. § 103(a) over Kim, Donovan, and Erickson. Appellants did not argue for the separate patentability of any of these rejected claims.

Claims 1-3, 5-6, 8-10, and 12 were rejected under 35 U.S.C. § 103(a) over Kim, Donovan, and Henrard. Appellants did not argue for the separate patentability of any of these rejected claims.

II. FINDINGS OF FACT

1. Appellants' claim 1 recites:

> A method for treating sympathetically maintained chronic pain, the method comprising:
>
> administering by percutaneous injection a therapeutically effective dose of a botulinum toxin type A, B, C_1, D, E, F, or G to a sympathetic ganglion of a human patient, thereby achieving a sympathetic block for an extended period of time.

(App. Br. 15, Claims App'x).

2. Kim teaches that botulinum toxin type A ("BTA") has sympathetic ganglion blocking effects that last for over one month in rabbits, without causing pathological changes in the ganglion. (Kim abstract).

3. Kim reports the results of studies in which BTA was injected into an exposed ganglion in the neck of a rabbit and the sympathetic response of varying pupil size ("miosis") was measured. (Kim p.9, ¶ 2.2).

4. Kim teaches that sympathetic ganglion block by BTA may be used to control sympathetically maintained pain. (Kim, p. 11, right col., last paragraph).

5. Kim does not teach administering botulinum toxin by percutaneous injection to a sympathetic ganglion of a human.

6. Donovan teaches administration of botulinum toxin to humans, generally for treating parathyroid disorders. (Donovan ¶ [0001] and [0088]-[0092]).

7. Donovan teaches that intractable pain in humans has been treated by percutaneous injection of substances into a ganglion to create a block. (Donovan ¶ [0090]).

III. ISSUE

Would those of skill in the art have found it obvious to administer botulinum toxin to treat chronic pain by achieving a sympathetic block for an extended period of time from the teachings of both Kim and Donovan?

IV. ANALYSIS

Appellants' claim 1 provides a method of treating chronic pain by injecting botulinum toxin to a sympathetic ganglion in a patient. (FF 1)[1].

Kim teaches that BTA can block sympathetic ganglions for over a month in rabbits without damaging the nerve (FF 2) and suggests that it might be used to control sympathetically maintained pain (FF 4). Kim does not provide experiments showing actual pain control in humans (FFs 3 and 5), but Donovan teaches that it was known that intractable pain can be treated with percutaneous injection of substances into human ganglia. (FF 7).

Those of skill in the art would have had reason to modify the teaching in Kim that BTA can block sympathetic nerves, with the teaching in Donovan that percutaneous injection of substances into human ganglia can

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[1] "FF" indicates a Finding of Fact.

reduce pain, because Donovan teaches how BTA can be administered. (FF 6).

Appellants argue that Kim does not teach administering botulinum toxin to result in a "sympathetic block," but instead uses the term "neurolytic," which Appellants assert means that it destroys neurons instead of blocking them. (App. Br. 4). Kim states that the results presented "imply that BTA may be used clinically as a safe sympathetic *neurolytic* agent," (Kim, p. 11, paragraph bridging right and left columns (emphasis added); *see also* p. 11, left col., last full paragraph), but we do not read this statement in the context of the rest of Kim to mean that it does not provide a "sympathetic block." "During examination, 'claims . . . are to be given their broadest reasonable interpretation consistent with the specification, and . . . claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.'" *In re American Academy of Sci. Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (citation omitted). Appellants cite to a dictionary definition of "neurolysis" (*see* App. Br. 4), but they do not explain why a "sympathetic block for an extended period of time" is not achieved by destroying the neuron, especially given that Appellants' claims do not limit the duration of the block. In fact, Appellants' specification states that "neurolytic techniques have also been used as a sympathetic block." (Spec. ¶ [09]). Thus, the broadest reasonable interpretation of the claim term "sympathetic block" would include a block produced by a neurolytic agent. We are not persuaded that Kim fails to teach that BTA can achieve a sympathetic block, as claimed.

Appellants also argue that Kim does not provide any expectation of success in using botulinum toxin to treat sympathetically maintained chronic

pain in humans, because it was known in the art that pupil dilation, or miosis, is not indicative of pain. (App. Br. 4-5). Appellants argue that the results in Kim are not reliable or consistent (App. Br. 6-7), citing Kim for a discussion of a "lack of close agreement between the BTA injection and resultant occurrence of miosis. . . ." (Kim, p. 11, left col., second full paragraph). Appellants cite to Onal, et al., 33 *Gen. Pharmacol.*, 83-89 (1999) ("Onal"), which states that when investigating analgesic drugs, "it is difficult to evaluate the analgesic response with the pupil diameter." (Onal abstract). According to Appellants, because Kim does not show a correlation between miosis and pain, those of skill in the art would not expect success from the results of BTA blockage reported. (App. Br. 4-5). More generally, Appellants argue that animal models for neuropathic pain are not necessarily predictive of human pain. (App. Br. 7).

We are not persuaded by these arguments since they take into account only the teachings of Kim. While Kim does postulate animal to animal variations for the dosages used and efficiency (*see id.* p. 11, left col., third full paragraph) and a "lack of close agreement between the BTA injection and resultant occurrence of miosis," Kim ultimately concludes that BTA showed sympathetic ganglion blocking effects in at least some animals. (FF 2). Taking into account the teachings of Kim along with Donovan's teaching that it was known to inject blocking substances into human ganglia to relieve pain, one skilled in the art would have expected that the block taught by Kim would work in humans when injected as taught by Donovan. (FF 7). Appellants have not provided sufficient evidence to show that when reading Kim *in light of Donovan*, those in the art would doubt that the

claimed method would work. (See App Br. 17, Evidence App'x ("There are no Exhibits.")).

Appellants argue that Donovan teaches using only neurolytic agents such as ethanol and phenol to treat pain, not botulinum toxin. (App. Br. 8). Appellants also argue that Donovan does not teach any correlation between relief of parathyroid or calcium disorders and relief of pain and does not report on any pain studies. (App. Br. 9). However, "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). The Examiner found that Kim shows botulinum toxin to be useful as a sympathetic ganglion blocking agent and thus Donovan need not have provided such a teaching. Donovan shows that such agents can be, and have been, effectively injected percutaneously into humans.

The Examiner did not err in rejecting claim 1 under 35 U.S.C. § 103(a) over Kim and Donovan.

The Examiner rejected claims 1-6 over Kim, Donovan, and Brushy (Ans. 5) and claims 1-3 and 5-7 over Kim, Donovan, and Erickson (Ans. 4-5), both under 35 U.S.C. § 103(a).

Appellants repeat the same arguments against the rejection of these claims as for claim 1 (*see* App. Br. 9-11). For reasons noted, we found these arguments to be unpersuasive. Appellants argue further that neither Brushy nor Erickson cures the deficiencies of Kim and Donovan because neither teaches that botulinum toxin would be useful in treating sympathetically maintained pain. (App. Br. 10-11). Because Appellants provide no new arguments against the rejection of claim 1 and do not dispute that Brushy

and Erickson teach the additional elements recited in these claims, Appellants have not shown that the Examiner erred.

The Examiner also rejected claims 1-3, 5-6, 8-10, and 12 over Kim, Donovan, and Henrard under 35 U.S.C. § 103(a). (Ans. 6). Appellants' claim 8 recites a method for treating cardiovascular conditions, the method comprising administering botulinum toxin type to a sympathetic ganglion of a human patient by percutaneous injection. (*See* App. Br. 16; Claims App'x).

Kim and Donovan were relied upon for the same reasons as discussed above in regard to the rejection of claim 1. Henrard was relied upon for teaching that angina pain from spasms of coronary arteries can be alleviated with surgery to interrupt a sympathetic nerve ganglion. (Henrard translation abstract).

Appellants argue that Henrard teaches a highly invasive procedure that produces a global effect, in contrast to the claimed method which impacts only a specific biochemical pathway. (App. Br. 12). According to Appellants, because of this difference, those in the art would not have had an expectation of success in using botulinum toxin to treat cardiovascular disease. (*Id.*). Appellants also repeat the same arguments against the rejection of claim 1. (*Id.*).

We are not persuaded by Appellants' arguments. Appellants are essentially arguing that none of the cited references alone renders the claimed method obvious, rather than addressing the combination of their teachings. *See Merck,* 800 F.2d at 1097. Henrard would have informed one skilled in the art that blockage of a sympathetic ganglion was one approach to treating peripheral vascular disease. Thus, one skilled in the art would

have had reason to use the blocking agents and injection method taught by Kim and Donovan for treating cardiovascular disease. Appellants have not shown that the Examiner erred.

V. ORDER

Upon consideration of the record and for the reasons given,

the rejection of claims 1-3 and 5-6 under 35 U.S.C. § 103(a) over Kim and Donovan is AFFIRMED;

the rejection of claims 1-6 under 35 U.S.C. § 103(a) over Kim, Donovan, and Brushey is AFFIRMED;

the rejection of claims 1-3 and 5-7 under 35 U.S.C. § 103(a) over Kim, Donovan, and Erickson is AFFIRMED; and

the rejection of claims 1-3, 5-6, 8-10, and 12 under 35 U.S.C. § 103(a) over Kim, Donovan, and Henrard is AFFIRMED.

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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